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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/810,385
Filing Date: March 16, 2001
Appellant(s): LAUGHON, ALLEN S.

Wisconsin Alumni Research Foundation
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed January 15, 2008 appealing from the Office action mailed November 30, 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

The Examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The amendment after final rejection filed on February 16, 2007 has not been entered.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

No evidence is relied upon by the Examiner in the rejection of the claims under appeal.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 9-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **THIS IS A NEW MATTER REJECTION**.

Section 1 of claim 9 contains the language "a promoter which is regulated by a TGF-β, activin or bone morphogenetic protein signal, wherein said cell co-expresses interacting proteins comprising a Smad protein, a DNA binding Smad co-repressor protein and a CtBP protein".

At most the passage contained within page 14, line 11 and page 15, line 12 mentions TGF-β- dependent reporter expression and one of ordinary skill in the art

could assume that expression must be directed by a TGF-β promoter, but as noted in the FAOM mailed June 14, 2006 that may not happen under the exclusivity of the TGF-β promoter. This section of the specification does not make mention of the activin or bone morphogenetic protein signal influencing transcription. Pages 9 and 10 of the specification do not exemplify the claimed method and pages 1-3 in no form or fashion seem to contemplate the claimed method implementing activin or a bone morphogenetic protein signal to regulate a promoter, which in turn directs transcription. While at best one of ordinary skill in the art can assume there is a TGF-β promoter involved in the claimed method, clearly there is no support for activin or bone morphogenetic protein signal regulating a promoter. It seems that none of the recited passages list the reporter with a TGF-β-dependent promoter or activin or bone morphogenetic protein signal within cells expressing specifically interacting proteins with the detection of transcription and the comparison between levels of transcription at precise points. The specification does not exemplify an experimental design of the claimed assay. The steps listed in the claims are not of record in the specification. The claims do not meet the written description requirement because the specification is remiss of active method steps including the cells containing interacting proteins and compounds necessitated for implementing the claimed method.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 9-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 9, section a, line 3 cites a "bone morphogenetic protein signal". It is not clear what this signal is and how it regulates a promoter. Accordingly, the metes and bounds cannot be determined.

(10) Response to Argument

Claim Rejections - 35 USC § 112, New Matter Rejection

Appellants state "the Examiner's reasoning seems to be that the specification does not exemplify the method and therefore, written description is not met", see page 5 of the Brief, last paragraph. Appellants' responses to the Examiner's assertions are lack of working examples is not an adequate basis for a written description rejection, cite case law, as well as cite the MPEP in support of their response. Appellants further argue by pointing out passages within the specification, specifically pages 9-12, 14 and 15, which purportedly support Appellants' claimed method and the required elements necessitated by the claimed invention, see Brief, page 6. Appellants assert their disclosure clearly supports the claimed invention and notes the teachings of Su et al. (Cancer Research 60: 3137-3142, 2000) illustrate the established use of promoters, such as the *wingless* promoter in screening assays, such as that claimed, see Brief, page 7.

Appellants arguments have continually set forth a course of reasoning based on passages in their specification where they allege when the specification is taken as a whole, clearly describes the claimed invention. The Examiner has reviewed the specified pages and lines, as well as the entire specification and has not found support for Appellants' contemplation of a method for identifying compounds comprising determining a first level of transcription detected in cells containing interacting proteins. There continues not to be any support for the claimed method to include "a promoter which is regulated by a TGF-β, activin or bone morphogenetic protein signal, wherein said cell co-expresses interacting proteins comprising a Smad protein, a DNA binding Smad co-repressor protein and a CtBP protein". None of the sections of the specification pointed out by Appellants support the cited contemplation in the manner set forth in claim 9. Appellants have pointed out scientific observations, as well as Su as support for their claimed method. Support should be based upon Applicant's own experimental design or original conception of an assay of record in the specification, and not a foretelling of how a method could be implemented.

Moreover, while it is true that the claimed subject matter need not be described literally it should be of record in the specification with the specific teachings as set forth in the claims. Namely at page 14, lines 11-21 there is the prophetic teaching that assays *can be* developed that interact with Smad protein to prevent interaction of CtBP with Smads or DNA-binding co-repressors or that interrupt the formation of a DNA-bound complex containing Smads, CtBP and DNA-binding co-repressors, however this is not support for the claims specifically setting forth a method. The claims do not meet

the written description requirement because the specification is remiss of active method steps including the cells containing interacting proteins and compounds necessitated for implementing the claimed method. The paragraph bridging pages 14 and 15 notes the reporter with a Smad box-containing promoter within cells containing specifically interacting proteins with the detection of transcription and the comparison between levels of transcription at precise points, however this does not aid in supporting the reporter and the Smad-box promoter. The steps listed in the claims are not of record in the specification. The claims do not meet the written description requirement because the specification is remiss of active method steps including the cells containing interacting proteins and compounds necessitated for implementing the claimed method.

Claim Rejections - 35 USC § 112, second paragraph

Appellants' reiterate the criteria regarding 35 U.S.C. 112, second paragraph established in the MPEP and assert the claim as a whole must be considered in order for one of ordinary skill in the art to determine the scope of the claim, see Brief, page 8. Appellants conclude arguments noting on page 4, lines 19-31 of the specification "...compounds identified by the instant assay interfere with transcriptional repression that otherwise would occur in response to signaling by TGFβ, activin or bone morphogenetic protein. As such, it is clear from this disclosure that ...bone morphogenetic protein signal includes a ...bone morphogenetic protein."

Reviewing Appellants' specification at the specified page and lines one or ordinary skill in the art observes a method of identifying compounds that interact with

Smad molecules to prevent interactions required for transcriptional repression in response to three molecules, including bone morphogenetic protein signal. There is no information presented or addressing how as claimed a bone morphogenetic protein *signal* impacts a reporter with a promoter, hence the claim is not clear and the metes and bound cannot be determined.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Alana M. Harris, Ph.D.

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